



RESPONSE UNDER 37 CFR 1.116  
EXPEDITED PROCEDURE  
EXAMINING GROUP 3700

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named	
Inventor	: Weston F. Harding
Appln. No.	: 10/828,964
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Title	: NEEDLELESS LUER ACCESS CONNECTOR
Docket No.	: B819.12-0010

Confirmation No.: 5397

Group Art Unit: 3763

Examiner:  
Vu, Quynh-Nhu Hoang

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

**Mail Stop AF**  
Commissioner For Patents  
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**INTRODUCTION**

This Request follows the final Office Action mailed December 26, 2008 and the Advisory Action mailed March 31, 2009. No amendment is filed with this Request, and the following remarks are presented to explain its basis. A Notice of Appeal and appropriate fees are enclosed.

**REMARKS**

Review is requested on the basis that the final Office Action commits factual errors in sustaining rejections of the pending claims (32-37). Neither McPhee nor Jepson anticipates the pending claims (32-37) as neither reference teaches or suggests a distal portion of a channel or a distal portion of a septum having an elliptical cross section while the other has a circular cross section, wherein the distal portion of the septum is biased by the distal portion of the channel because the distal portion of the septum is forced to conform to the different cross section of the distal portion of the channel. Removal of the erroneous rejections is respectfully requested.

In the final Office Action, claims 32-33 and 35-36 were rejected under 35 U.S.C. § 102(b) as being anticipated by McPhee (U.S. Patent No. 5,199,948). Claims 32-37 were rejected under 35 U.S.C. § 102(e) as being anticipated by Jepson et al. (U.S. Pat. No. 6,344,033). The Office Action commits factual errors in sustaining these rejections under § 102 because neither McPhee nor Jepson anticipate every element of the pending claims. Specifically, neither McPhee nor Jepson teaches or suggests either a **distal** portion of a channel or a **distal** portion of a septum having an elliptical cross section, wherein the **distal** portion of the septum is biased by the differently shaped **distal** portion of the channel as explicitly required by the pending claims. In the Figures of present application, as well as those of McPhee and Jepson, the **proximal** portion is depicted as the top end and the **distal** portion is depicted as the bottom end because “distal” refers to a portion of the connector further from its connection to an IV source and closer to the patient.

Independent claim 32, for example, requires distal portion 23 of septum 20 has a *substantially circular cross-section* and distal portion of channel 13 has a *substantially elliptical shape*. As a result, distal portion 23 of septum 20 is biased to a substantially elliptical shape by distal portion of the channel 13. This biasing of distal portion 23 of septum 20 causes a portion of longitudinal slit 25 in distal portion 23 of septum 20 to be closed. The biasing of circular distal portion 23 of septum 20 to a closed position is illustrated in FIG. 38, while an open unstressed state is depicted in FIG 42. The language of claim 32 specifically recites: “*the channel has a substantially elliptical cross section* having a major axis and a minor axis along at least a distal portion thereof and the distal portion of the septum is located in and restrained by a distal portion of the channel such that *the distal portion of the septum is biased into a substantially elliptical shape by the distal portion of the channel* and a portion of the longitudinal slit in the distal portion of the septum is closed”. Emphasis added.

Independent claim 35 is similar to claim 32 recited above except that the shapes of septum and channel are reversed: distal portion 23 of septum 20 has a *substantially elliptical cross-section* and distal portion of channel 13 has a *substantially circular cross-section*. As a result, distal portion 23 of septum 20 is biased into a substantially circular shape by distal portion of channel 13 and a portion of the longitudinal slit 25 in distal portion 23 of septum 20 is closed. The biasing of

elliptical distal portion 23 of septum 20 to a closed position is illustrated in FIG. 37, while an open unstressed state is depicted in FIG. 40. The language of claim 35 specifically recites: "*the channel has a substantially circular cross section along at least a distal portion thereof and the distal portion of the septum is located in and restrained by a distal portion of the channel such that the distal portion of the septum is biased into a substantially circular shape by the distal portion of the channel and a portion of the longitudinal slit in the distal portion of the septum is closed*". Emphasis added.

The final Office Action contends that McPhee anticipates claims 32 and 35, but the final Office action fails to identify the portions of McPhee that allegedly meet the above recited elements of claims 32<sup>1</sup> and 35<sup>2</sup>. McPhee fails to show the elements of claim 32 and 35 for at least the following reasons. McPhee compresses longitudinal slit 33 of septum 15 by press fitting peripheral flange 29 into the retaining cap 17 at the *proximal end* of housing 13. McPhee '948; FIGS. 1-2; col. 3, ll. 48 – col. 4, ll. 6, emphasis added. Tapered distal tip 31 of septum 15 is circular in cross section and spaced apart from wall 24, which is also circular in cross section. McPhee '948; FIGS. 1-3; col. 4, ll. 7-13. Since McPhee discloses the distal portions of septum and housing are **both circular**, no biasing force could occur from a difference in shape at the distal end of recess 23. Even in FIG. 7, where distal portion of septum 81 has concave surface 87, which bulges to become flat surface 87a, the biasing force is still applied at proximal end 83 by cap 17a. McPhee '948; FIG. 7; col. 5, ll. 32-47. The Office Action commits a factual error in sustaining a rejection of claims 32-

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<sup>1</sup> With respect to claim 32, the final Office Action neglects to identify (a) a channel having a substantially elliptical cross section having a major axis and a minor axis along at least a distal portion thereof, (b) a medial portion of a septum having a cross section less than a cross section of the top portion and less than the cross section of the channel, and (c) a distal portion of the septum defining a substantially circular cross section in its unstressed condition, wherein (d) the distal portion of the septum is located in and restrained by a distal portion of the channel and a portion of the longitudinal slit in the distal portion of the septum is closed.

<sup>2</sup> With respect to claim 35, the final Office Action neglects to identify (a) a septum having a distal portion defining a substantially elliptical cross section with a major axis and a minor axis in its unstressed condition, (b) a channel having a substantially circular cross section along at least a distal portion thereof, and (c) the distal portion of the septum located in and restrained by the distal portion of the channel such that the distal portion of the septum is biased into a substantially circular shape and a portion of the longitudinal slit in the distal portion of the septum is closed.

33 and 35-36 under §102(b) because McPhee fails to teach or suggest every element of claims 32-33 and 35-36.

The final Office Action further contends that Jepson anticipates claims 32 and 35, but again neglects to identify the portions of Jepson that allegedly meet the above recited elements of claims 32<sup>3</sup> and 35<sup>4</sup>. Jepson fails to disclose the elements of claims 32 and 35 for at least the following reasons. In Jepson, central portion 34 of septum 28 is elastically restrained relative to housing 26 at upper end 30, or at a *proximal portion* of housing 26. Jepson '033; FIG. 1; col. 8, ll.25-58, emphasis added. Lower (distal) portion 40 of septum 28 has a generally **rectangular** cross section and vertically extending side walls 28 are tapered. Jepson '033; FIGS. 3-3a; col. 8, ll.62 – col. 9, ll. 5. The final Office Action generally references FIG. 13, but in FIG. 13 lower portion 410 of septum 402 is conically shaped, open ended, and sealed to housing 418 in a manner that prevents the ability to bias slit 414 closed. Jepson '033; FIG. 13; col. 18, ll. 47 – col. 19, ll. 7. The Office Action commits a factual error in sustaining a rejection of claims 32-37 under §102(e) because Jepson fails to teach or suggest every element of claims 32-37.

Also in the final Office Action, claims 34 and 37 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 34 and 37 are in full compliance with the written description requirement because both claims are supported by Figures 40 and 42, as well as the specification as published (pg. 8, col. 15-16, para. 88) as delineated on pages 5-6 of previously submitted Amendment After Final filed March 26, 2009, which is hereby

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<sup>3</sup> With respect to claim 32, the final Office Action neglects to identify (a) a channel having a substantially elliptical cross section having a major axis and a minor axis along at least a distal portion thereof, and (b) a distal portion of the septum defining a substantially circular cross section in its unstressed condition, wherein (c) the distal portion of the septum is located in and restrained by a distal portion of the channel and a portion of the longitudinal slit in the distal portion of the septum is closed.

<sup>4</sup> With respect to claim 35, the final Office Action neglects to identify (a) a distal portion of a septum having a substantially elliptical cross section with a major axis and a minor axis in its unstressed position, (b) a channel having a substantially circular cross section along at least a distal portion thereof, and (c) the distal portion of the septum is located in and restrained by the distal portion of the channel such that the distal portion of the septum is biased into a substantially circular shape and a portion of the longitudinal slit in the distal portion of the septum is closed.

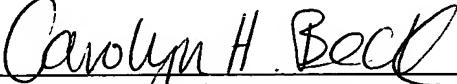
incorporated by reference. The Office Action commits a factual error by maintaining the §112 rejection of claims 34 and 37.

Claims 32-37 are allowable because the claim language specifically requires a distal portion of a channel or a distal portion of a septum having an elliptical cross section while the other has a circular cross section. This difference in shape results in the distal portion of the septum being forced to conform to the differently shaped cross section of the distal portion of the channel, which is not taught or suggested by the prior art on record. In contrast, McPhee and Jepson both disclose force applied at a proximal end of septum by a press-fit relationship with a proximal end of housing. Since McPhee and Jepson do not disclose all of the elements of claims 32-37, the anticipation rejections should be withdrawn. In view of the foregoing, a finding in favor of allowance is requested.

Respectfully submitted,  
KINNEY & LANGE, P.A.

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